



# PRAPOUNDAREEKADI GHRITA, A NOVEL FORMULATION FOR THE MANAGEMENT OF PARIKARTIKA (ACUTE ANAL FISSURE)

\*P. Sreenadh<sup>1</sup>, Mahanta V.D.<sup>2</sup>, Sherkhane R.<sup>3</sup>

<sup>1</sup> Ph.D. Scholar, Dept. of Shalya Tantra, Institute of Teaching and Research in Ayurveda (Institute of National Importance), Jamnagar, India

<sup>2</sup> Associate Professor, Dept. of Shalya Tantra, All India Institute of Ayurveda, New Delhi, India

<sup>3</sup> Professor, Dept. of Shalya Tantra, Banaras Hindu University, Varanasi, India

## ABSTRACT

Anal fissure is a common medical condition characterized by a tear or ulcer in the anal canal. It comprises 10-15% of anorectal disorders. The healing process of an acute anal fissure differs from that of a typical acute wound due to continuous contamination of the fissure and reduced blood supply caused by sphincter spasm, leading to chronicity. Currently available treatments include conservative measures, such as dietary changes and stool softeners, as well as topical medications and surgical interventions. However, these treatments often have drawbacks, such as limited efficacy, adverse effects, and invasiveness. The purpose of this research was to evaluate the comparative efficacy of *Prapoundareekadi Ghrita* and *Jatyadi Ghrita* in the management of acute anal fissure. The study findings indicate that *Prapoundareekadi Ghrita* is as effective as *Jatyadi Ghrita* in the management of acute anal fissure with an overall efficacy of 90% in promoting healing and relieving symptoms. No adverse reactions were observed in either group, highlighting the safety profile of the trial drug. In conclusion, *Prapoundareekadi Ghrita* represents a convenient and therapeutically efficient alternative for the treatment of acute anal fissure. Its simplicity in formulation, containing fewer ingredients compared to the controlled drug, renders it a superior option in this context. The study results support the use of *Prapoundareekadi Ghrita* as an effective and safe treatment option, potentially addressing the drawbacks associated with current treatments for anal fissure.

**KEYWORDS:** Parikartika, Acute anal fissure, Prapoundareekadi Ghrita, Jatyadi Ghrita

## INTRODUCTION

*Parikartika* is a common painful condition of anus and is compared with anal fissure in modern medicine. According to *Kashyapa*, patients suffering from *Parikartika* will have cutting and tearing pain in *GudaPradesha*.<sup>1</sup> *Charaka*,<sup>2,3</sup> *Vagbhata*<sup>4</sup> and *Susruta*<sup>5,6,7</sup> mentioned it in the context of *Vamana Virechana Vyapat* and *Vasti Vyapat* whereas *Kashyapa* explained it in the framework of *Antarvartni Chikitsa* and *Garbhini Chikitsa*. *Susruta* also included *Parikartika* in the *Purvarupa of Arsha*.<sup>8</sup>

Anal fissure is a linear split in the distal part of anoderm. They are associated with severe pain during defecation, constipation and streaks of blood on faeces. Pain is so severe that patient often reluctant for defecation due to the fear of pain. Posterior midline is commonly involved in the pathology of anal fissure. It is predisposed by constipation, increased sphincter tone, abuse use of laxatives etc. It comprises 10-15% of anorectal disorders.<sup>9,10</sup> This condition mostly occurs between 30-50 years of age.<sup>9</sup>

Despite the considerable advancements in modern surgery, the treatment of anal fissures still necessitates medicines with superior wound healing properties and the ability to alleviate sphincter spasm. Available modalities include pharmacological options (glyceryl trinitrate, botulinum toxin, calcium channel antagonists, etc.) and surgical procedures (Fissurectomy, lateral internal sphincterotomy, sphincter stretch, etc.). However, these approaches suffer from drawbacks, including delayed wound healing, recurrence, side effects (e.g., headaches from botulinum toxin), and the risk of post-anesthetic complications associated with surgical interventions.<sup>11,12,13,14</sup>

There are plenty of unexplored Ayurvedic formulations present in various *Samhitas* which are indicated for *Vrana Shodhana* and *Ropana*. Considering the *dosha* involvement, a search for an unexplored Ayurvedic formulation which acts mainly on *Pitta*, *Vata* and *Rakta* reached into *Prapoundareekadi Ghrita*, explained by *Acharya Susruta* in *Paithika Vidradhi Chikitsa* context.<sup>15</sup>

## METHODOLOGY

### Research question:

What is the efficacy of local application of *Prapoundareekadi Ghrita* in comparison with *Jatyadi Ghrita* in the management of Acute Fissure in ano?

### Null hypothesis (H<sub>0</sub>):

The local application of *Prapoundareekadi Ghrita*, once daily for a period of 15 days will not heal acute Fissure-in-ano better than *Jatyadi Ghrita*.

### Alternative hypothesis (H<sub>1</sub>):

If null hypothesis is rejected, alternate hypothesis will be accepted i.e. *Prapoundareekadi Ghrita* will heal acute Fissure-in-ano better than *Jatyadi*

*Ghrta*.

### Aims & objectives of the research project

#### Primary

- To compare the efficacy of local application of *Prapoundareekadi Ghrita* and *Jatyadi Ghrita* in the management of Parikartika (Acute Fissure-in-ano).

#### Secondary:

- To observe recurrence in the follow up period of one month.

The study got approved by Institutional Ethics Committee (IEC-AIIA/2019-PG-121) and was registered in Clinical Trials Registry Of India (CTRI/2020/03/024260).

### Grouping and posology

A total of 20 patients of acute anal fissure were randomly divided into two groups based on computer generated random number table. Patients in group A were treated with Local application of *Prapoundareekadi Ghrita* once daily for a period of 15 days. Patients in group B were treated with local application of *Jatyadi Ghrita* once daily for a period of 15 days. In both the groups, one teaspoon (approximately 5 grams) of *Triphala churna* (powder of dried fruits of *Terminalia chebula*, *Phyllanthus emblica* and *Terminalia bellirica*) was given with warm water after food, at night. After the 15<sup>th</sup> day, 2 follow ups were taken with an interval of 15 days to assess the health of the patient in terms of recurrence of the symptoms or any adverse effects. The follow-up study was completed in 30 days.

### Diagnostic criteria

- Moderate to severe pain as feels like tearing/cutting pain made by "knife" or "razor blade" in anal region during defecation.
- Hematochezia (Usually described as the blood streaks on feces).
- Intense and painful anal spasm lasting for several hours after stool evacuation.

Inclusion criteria	Exclusion criteria
Patients of both gender between the age group of 16 and 50 years was included irrespective of their <i>Prakriti</i> , <i>Sara</i> , Religion, Education and Socio-economic status.	Fissure in ano due to secondary causes such as Crohn's Disease, HIV, Ulcerative Colitis, Carcinoma of Rectum, Tuberculosis.
Passage of bright streaks of blood along with stool	Fissure in ano associated with Haemorrhoids, Fistula -in-ano.
Pain on defecation	Chronic Fissure -in-ano
Onset of the symptoms within 6 weeks.	Uncontrolled Diabetes Mellitus.

**Table 01 : Inclusion criteria and exclusion criteria**

**Investigations**

Routine blood investigations including complete blood count, erythrocyte sedimentation rate, biochemical investigations such as fasting blood sugar, post prandial blood sugar, serological investigations including HIV, HBsAg, HCV and VDRL were carried out before enrolling the patients.

**Ingredients of Prapoundareekadi Ghrita**

Sanskrit name	Botanical name	Parts used
Prapoundareeka	<i>Nelumbo nucifera Gaetm.</i>	Stamens
Manjishta	<i>Rubia Cordifolia</i>	Root
Yasthimadhu	<i>Glycyrrhiza glabra Linn.</i>	Root
Ushira	<i>Vetiveria zizanioides (Linn.)</i>	Root
Padmaka	<i>Prunus cerasoides D.Don</i>	Stem
Haridra.	<i>Curcuma Longa</i>	Rhizome
Goghrita	Cows's ghee	-
Goksheera	Cow's milk	-

**Table 02 : Ingredients of Prapoundareekadi Ghrita****Collection of raw drugs and preparation of Prapoundareekadi Ghrita**

The ingredients were collected from Kerala and Rajasthan. Drug authentication was done from National Institute of Science Communication and Information Resources (NISCAIR), New Delhi. Prapoundareekadi Ghrita was prepared based on the principles of ghrtapaka vidhi by Acharya Sharangadhara.<sup>16</sup> This *Yoga* contains *Ksheera* as *Dravadravya*. Therefore the ratio of ingredients were modified accordingly.

375g *kalka* (62.5g each drugs), 3 kg *go Ghrita*, 12 Litres of *Goksheera* and 12 Litres of *Jala* was taken for the preparation of *Prapoundareekadi Ghrita*. The *Ghrita* was warmed to 70 degrees. Then bowls of *Kalka* was added into it and the flame was set to medium. The milk was heated to 70 degrees in another vessel. After that the milk was slowly added to the mixture of *Ghrita* and *Kalka* and cooked till *Kharapaka Lakshanas* were obtained. After *Swangasheeta*, it was filtered and measured. The weight of final product was 2.60kg. It was then stored in an airtight container. Jatyadi Ghrita was procured from GMP registered pharmacy (Vaidyaratnam Oushadha shala)

**Assessment criteria**

The findings were recorded in specially designed proforma.

- **Pain measurement (VAS)**
- **Peri anal itching (*Guda Kandu*):**
  - 0 : No itching
  - 1 : Itching for one hour after defecation.
  - 2 : Itching for 3-5 hours after defecation.
  - 3 : Persistent itching
- **Bleeding per rectum:**
  - 0 : Nil / spotless gauze
  - 1 : Few drops of blood on gauze (2"×2")
  - 2 : Half gauze wetted with discharge (2"×2")
  - 3 : Total gauze wetted with discharge (2"×2")
- **Ulcer in ano:**
  - 0: No ulcer
  - 1 : Clean and healthy ulcer
  - 2 : Presence of ulcer with indurated margins
  - 3 : Presence of ulcer with indurated margins and slough
- **Formation of granulation tissue:**
  - 0 : Complete layer of epithelial covering on wound.
  - 1 : Granulation tissue on wound
  - 2 : Fresh wound with inflammation.
- **Sphincter activity:**
  - 0 : Normal
  - 1 : Hypertonic

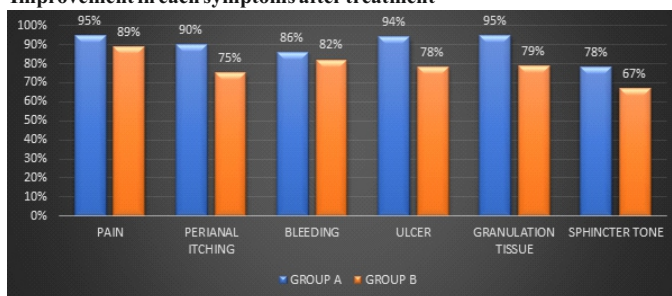
**STATISTICAL ANALYSIS**

The data obtained from the study were subjected to statistical analysis. Objective parameters were analyzed within the group by paired 't' test whereas those between the groups were analyzed by unpaired 't' test. Subjective parameters were analyzed within the group by Wilcoxon's signed rank test whereas those between the groups were analyzed by Manwhitney's test. The information collected on the basis of observations, were subjected to statistical analysis in terms of percentage of relief, Mean, Standard Deviation (SD), Standard Error (SE) and by the use of student unpaired 't' test evaluate the significance at different levels i.e., at 0.05, 0.01, and 0.001 levels. The obtained results were interpreted as – p value > 0.05 insignificant, p<0.05 significant and p<0.001

highly significant.

**OBSERVATION AND RESULTS**

Category		Percentage of cases in Group A	Percentage of cases in Group B
<b>Doshas involved</b>	<i>Vata</i>	100%	100%
	<i>Pitta</i>	100%	100%
	<i>Kapha</i>	70%	80%
<b>Mean age</b>		33.8 years	31.5 years
<b>Diet</b>	Veg	40%	10%
	Mixed	60%	90%
<b>Type of pain</b>	Pricking	30%	30%
	Cutting	20%	40%
	Burning	50%	40%
<b>Severity of pain</b>	Moderate	20%	40%
	Severe	80%	60%
<b>Bleeding</b>	Present	70%	90%
	Absent	30%	10%
<b>Perianal itching</b>	Present	70%	40%
	Absent	30%	60%
<b>Passing of stool</b>	Painful & regular	90%	70%
	Painful & irregular	10%	30%
<b>Number of ulcers</b>	Single	100%	100%
	Multiple	00%	00%
<b>Position of fissure</b>	6' o clock	80%	80%
	12' o clock	20%	20%

**Table 03 : Observations****Improvement in each symptoms after treatment****Graph 01: Percentage of improvements in each groups after treatment****Group A**

PARAMETERS	GROUP A			GROUP B		
	n	MEAN (S.D.)	p value	MEAN (S.D.)	p value	
Pain	10	BT 7.8(0.92)	0.006	BT 7.60(1.17)	0.006	
		AT 0.4(0.84)		AT 0.90(1.66)		
Itching	10	BT 1(0.94)	<0.05	BT 0.40(0.52)	0.14	
		AT 0.1(0.32)		AT 0.10(0.32)		
Bleeding	10	BT 0.70(0.48)	0.005	BT 1.10(0.57)	<0.001	
		AT 0.10(0.32)		AT 0.20(0.42)		
Ulcer	10	BT 1.50(0.53)	<0.001	BT 1.80(0.42)	<0.001	
		AT 0.10(0.32)		AT 0.40(0.70)		
Granulation tissue	10	BT 1.80(0.42)	<0.001	BT 1.90(0.32)	<0.001	
		AT 0.20(0.32)		AT 0.40(0.70)		
Sphincter tone	10	BT 0.90(0.32)	0.001	BT 0.90(0.32)	0.005	
		AT 0.20(0.42)		AT 0.30(0.48)		

**Table 04 : Results in group A and group B**

## Comparative efficacy between two groups

Criteria	Group	N	Mean(S.D.)	S.E.	P value
Pain	A	10	7.4(1.17)	0.37	0.33
	B	10	6.7(1.63)	0.51	
Itching	A	10	0.9(0.99)	0.31	0.13
	B	10	0.30(0.48)	0.15	
Bleeding	A	10	0.6(0.51)	0.16	0.23
	B	10	0.9(0.56)	0.18	
Ulcer	A	10	1.4(0.51)	0.16	1.00
	B	10	1.4(0.69)	0.22	
Granulation Tissue	A	10	1.70(0.48)	0.15	0.47
	B	10	1.5(0.7)	0.22	
Sphincter tone	A	10	0.2(0.42)	0.13	0.07
	B	10	0.6(0.51)	0.16	

Table 05: Comparative efficacy between two groups

## DISCUSSION

Occurrence of anal fissure in old age is naturally diminished due to the laxity of external sphincter in old age. Intake of mixed diet (in comparison with vegetarian diet) carries more chance of developing anal fissure. This may be because of less ingestion of dietary fibers in those who followed mixed diet that causes them constipation and eventually anal fissure. All patients suffered from either painful defecation, incomplete defecation, or both. In this study all patients had *dushti* of both *Vata* and *Pitta*, which is responsible for various types of pain such as cutting, pricking, and burning pain in different patients (Table 03). This finding proves that *shamana* of *Vata* and *Pitta* are more important in reducing the symptoms of anal fissure.

*Prapoundareeka* (Nelumbo nucifera) possess free radical scavenging effect, regulates subcutaneous fat metabolism, inhibits the action of elastase, has antibacterial properties against *Escherichia coli*, *Staphylococcus aureus* etc and exhibit anti-inflammatory activity.<sup>17</sup> Topical application of *manjishtha* helps in early epidermal and dermal regeneration by increased infiltration of inflammatory cells, blood vessel formation and enhanced proliferation of cells.<sup>18</sup> Tannins and anthraquinones present in *Rubia Cordifolia* have antioxidant and blood purifying properties. Phyto-pharmacological perspectives of *Yashtimadhu* showed ulcer healing activity, antioxidant property and antibacterial effects.<sup>19,20</sup> *Usheera* contains a variety of chemical constituents such as flavonoids, phenolic acids etc. They exhibit anti-inflammatory, antiulcer, antioxidant, anti-allergic and antiviral properties. Scavenging of oxygen free radicals are the important effect of flavonoids.<sup>21</sup> Various studies demonstrated antioxidant, analgesic, antispasmodic activities of *padmaka*.<sup>22,23</sup> *Haridra* is antibacterial, antiseptic, antifungal anti-inflammatory and blood purifying effect. These attributes help in early wound healing and contraction.

*Goghrita* helps in *Vranaropana*. lipophilic activity of *Ghritha* helps in easy transportation to a target organ and final delivery inside the cell. So, *Goghrita* helps facilitates entry of components of formulation into the cell by crossing the cell wall.<sup>24</sup> *Goghrita* also contains beta carotene and vitamin E, both are known as antioxidants.<sup>25</sup>

*Prapoundareeka Ghritha* has *tikta*, *Madhura* and *kashaya rasa*, *laghu* and *snigdha guna* and *sheeta virya*. *Madhura rasa* has *dhatuvardhana* (tissue growth), *preenana* (nutrition) and *poshana* (nourishment) effects. This helps in the regeneration of cells, contraction of wound and epithelialization. *Tikta* and *Kashaya rasa* exhibits *Raktashodhana* (blood purifying) property. *Raktashodhana* and *varnya* properties helps to improve local blood circulation. *Kashaya rasa* also has *visada guna* which helps in *lekhana karma* (scraping of slough) from wound. *Snigdha guna* counteracts the aggravated *Vata Dosh*, whereas *Madhura*, *Tikta* and *Kashaya rasa* does the *shamana* of *Pitta* and *Rakta*. *Sheeta virya* of drug helps in reducing the *Pitta* and inflammatory changes.<sup>26</sup>

## CONCLUSION

The healing process of an acute anal fissure differs from that of a typical acute wound due to continuous contamination of the fissure and reduced blood supply caused by sphincter spasm, resulting in chronicity. This study concludes that *Prapoundareekadi Ghritha* is as effective as *Jatyadi Ghritha* in improving the key characteristics of acute anal fissure, with an overall efficacy of 90%. No adverse reactions were observed in either group. There was no statistically significant difference between both drugs (Table 05). Hence null hypothesis was accepted. However *Prapoundareekadi Ghritha* showed better outcomes clinically (Graph 01). The trial drug's simplicity in formulation, containing fewer ingredients than the controlled drug, makes it a convenient and therapeutically efficient alternative for treating acute anal fissure.

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